

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC**

<h1 style="margin: 0;">FSIS DIRECTIVE</h1>	8010.5	6/5/07
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CASE REFERRAL AND DISPOSITION

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 5, 2007.

I. PURPOSE

A. This directive describes the procedures and methodologies that are to be followed by the Food Safety and Inspection Service's (FSIS) Compliance and Investigations Division (CID) and Evaluation and Enforcement Division (EED), Office of Program Evaluation, Enforcement and Review (OPEER), for determining actions on Reports of Investigations (ROI), including referral to the Office of the General Counsel (OGC) and the Department of Justice (DOJ) for criminal, civil, and administrative enforcement actions.

B. Section VI. of this directive addresses the review of the ROI. Section VII. explains how to refer cases to EED. Section VIII. sets out possible enforcement actions. Sections IX. and X. address seizures of product and custom exempt operations, respectively. Section XI. defines Notices of Warning (NOW). Section XII. describes Letters of Information (LOI). Section XIII. explains how to refer actions to other agencies.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

Federal Meat Inspection Act (FMIA), (21 U.S.C. 601 et seq.)
Poultry Products Inspection Act (PPIA), (21 U.S.C. 451 et seq.)
Egg Products Inspection Act (EPIA), (21 U.S.C. 1031 et seq.)
Humane Methods of Slaughter Act (HMSA), (7 U.S.C. 1901-1907)
Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621, et seq.)
21 U.S.C. 458(a)(3)
9 CFR Sections 320.4, 381.146, 381.178 and 590.200
FSIS Directive 5930.1, Custom Exempt Review Process
FSIS Directive 8010.1, Methodology for Conducting In-Commerce Surveillance Activities
FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal

DISTRIBUTION: electronic

OPI: OPPED

V. BACKGROUND

The Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA) (the Acts) provide FSIS with the authority for criminal, civil, and administrative enforcement actions and sanctions against individuals and firms that have violated these statutes. Criminal, civil and administrative enforcement actions help to prevent adulterated, misbranded, or otherwise unsafe meat, poultry and egg products from reaching consumers, gain compliance, restrain and deter violations, and, in appropriate cases, sanction violators of the FMIA, PPIA and EPIA. FSIS takes administrative enforcement actions and recommends criminal and civil enforcement actions through OGC, the Office of the Inspector General (OIG), and DOJ.

VI. REVIEW OF THE ROI

A. Investigators are to:

1. complete the ROI and submit it to the Supervisory Investigator (SI) and the Regional Manager (RM) or designee for review and action in accordance with FSIS Directive 8010.4, "Report of Investigation."

B. Regional Managers (or designees) are to:

1. review the ROI for completeness and make a determination on the appropriate action or referral;

2. using the criteria in the Memorandum of Understanding (MOU) with the OIG, determine whether he or she should provide a copy of the information obtained in the case to OIG;

3. refer the ROI to EED when it describes violations that warrant evaluation for criminal, civil, or administrative enforcement action;

4. issue a NOW (see section XI.) letter for minor violations; and

5. issue an LOI (see section XII.), recommend continued verification through in-commerce surveillance activities, or close the case with no action.

NOTE: This OPEER LOI is different from an Office of Field Operations (LOI), which is issued regarding Notices of Intended Enforcement Actions (NOIE).

VII. CASE REFERRAL TO EED

A. An ROI that describes repeated or serious violations of the FMIA, PPIA, or EPIA that warrant evaluation for criminal, civil or administrative enforcement actions is to be referred to EED. Examples of situations in which an ROI is to be referred to EED for evaluation for enforcement actions include, but are not limited to, violations involving product adulteration or misbranding that pose a threat to the public health and safety of

consumers; distribution of adulterated products; gross negligence in sanitation, handling, storage, or distribution of products that has the effect of causing product adulteration; violations involving economic fraud or intent to defraud; and convictions of applicants for or recipients of Federal inspection.

B. Regional Managers (or designees) are to refer the ROI to EED when it shows violations that warrant evaluation for criminal, civil, or administrative enforcement action. They are to do so by:

1. preparing a transmittal memo to the attention of the Director of EED summarizing the evidence of the case and stating the recommended action (e.g., prosecution, injunction, other), when applicable; and

2. sending a copy of the ROI or other documentation to support the recommended action to the Director of EED.

NOTE: Case evidence may be submitted electronically or by hard copy; however, EED, OGC, or the U.S. Attorney may require the original evidence before proceeding with action.

VIII. ENFORCEMENT ACTIONS

A. OPEER, EED Director (or designee) will:

1. review the case evidence and recommendations to determine whether to take administrative enforcement action or to initiate criminal and civil enforcement action through OGC and the U.S. Attorney, issue a NOW, or close the case if the evidence does not support enforcement action;

2. when necessary, contact the RM, SI or Investigator to discuss the case findings and the sufficiency of the evidence upon completion of the case review;

3. issue a "Present Your View" (PYV) or "Show Cause" letter to the responsible individuals, when applicable. The PYV or "Show Cause" letter affords the responsible individuals and firms the opportunity to present their views and information regarding the allegations in question or to show cause as to why enforcement proceedings should not be initiated;

4. refer criminal, civil, and administrative cases to OGC and the U.S. Attorney, when appropriate;

5. coordinate communication between EED, OGC, and the RM, SI, or Investigator as necessary, to discuss evidence sufficiency or address any concerns;

6. assist OGC in the preparation of a formal referral to the U.S. Attorney;

7. ensure communication between OGC and the RM, SI, or Investigator to discuss case presentation strategies, desired outcomes, and other issues, before presenting the case to the U.S. Attorney;

8. work with OGC and the appropriate U.S. Attorney's Office within DOJ to draft supporting affidavits, complaints, indictments, and other documents needed or to develop disposition proposals such as plea agreements, pretrial diversions, consent decrees and other proposed actions;

9. ensure consistency and effectiveness in criminal, civil, and administrative enforcement actions and sanctions; and

10. coordinate follow-up surveillance or other activities with the RM, SI or Investigator to determine compliance with case settlement terms once actions are completed.

B. Regional Managers (or designees) are to:

1. participate in conference calls with EED and OGC to discuss case findings and evidence sufficiency and to address any concerns after completion of the case review;

2. direct the SI and Investigator in the development of case presentation strategies when requested by EED;

3. as necessary, participate with the SI and Investigator in presenting the case to the U.S. Attorney; and

4. monitor and ensure that the Investigator makes periodic (e.g., monthly) contacts with the U.S. Attorney to obtain information on case status.

C. Investigators are to:

1. participate in conference calls with EED and OGC to discuss case findings and evidence sufficiency and to address any concerns;

2. develop case presentation strategies to present case findings to the U.S. Attorney;

3. present case findings to the U.S. Attorney;

4. obtain information from EED regarding precedent cases involving similar violations that have led to successful outcomes;

5. as necessary, serve legal documents, attest to case evidence, or serve as a witness in legal proceedings;

6. keep EED fully informed about case activities and developments;

7. obtain certified copies of all court documents and provide copies to EED as soon as practical; and

8. verify compliance of settlement terms by firms and individuals once actions are completed.

IX. SEIZURES

For case actions regarding seizure requests, refer to FSIS Directive 8410.1, "Detention and Seizure."

X. CUSTOM EXEMPT OPERATIONS

For case actions regarding custom exempt operations, refer to FSIS Directive 5930.1, "Custom Exempt Review Process."

XI. NOTICE OF WARNING

A NOW provides notice of violations to firms and responsible individuals. A NOW is issued for a minor violation or when the violation is not serious enough to proceed with civil, criminal or administrative proceedings. The NOW identifies the violative conduct, condition, practice, or product; provides the opportunity to achieve voluntary compliance; and is sent to the firm and the most responsible official. Examples of minor violations include, but are not limited to, situations involving improperly labeled product with no intent to defraud and no public health risk.

A. Regional Managers (or designees) are to:

1. prepare the NOW for issuance to each subject of the ROI within ten (10) days of the completion of the ROI by the Investigator.
2. The NOW is to include the name of the firm, responsible official and title, and the address of the firm or responsible official. The NOW is also to:
 - a. state that there is an ROI that evidences that a violation of one or more of the Acts has occurred;
 - b. use FMIA, PPIA, EPIA and U.S. Code citations, as appropriate;
 - c. include a specific description of the alleged violation (i.e., who, what, when, and where) and the date the violation was discussed with the subjects;
 - d. briefly explain the requirements of the Acts and regulations, as applicable, and FSIS' enforcement authorities; and
 - e. explain the Agency's expectations of compliance and advise of possible penalties or future sanctions.
3. follow these guidelines when the individual or firm receiving the NOW questions the issuance of the NOW:
 - a. proceed to explain the violations and reason for issuance;

b. prepare a memorandum of conversation summarizing the discussion;
and

c. issue a letter to the attention of the individual summarizing the discussion and advising that if the individual wishes to appeal the decision, he or she is to prepare a letter of appeal and submit it to the Director of EED. The letter should provide contact information for the Director of EED.

NOTE: A case requiring issuance of a NOW involving two Regional Offices is to be prepared as completely as possible by the Investigator in the Regional Office where the violation was discovered. All documentation is then sent through the RM of that office for submission to the second Regional Office where the violator is located for completion. The RM in the second Regional Office assigns a case number and issues a NOW to each violator in his/her Region and forwards a copy of the completed report, including a copy of each NOW, to the RM in the first Region. Upon receipt of the completed case, the RM in the first Regional Office issues a NOW to each violator in his/her Regional Office following the above guidelines.

B. The EED Director (or designee) is to:

1. issue a NOW when he or she determines that the evidence in an ROI referred by the RM or designee does not support criminal, civil, or administrative enforcement actions;

2. issue a NOW in instances where the ROI documents minor violations of the Act;

3. issue a NOW letter in instances when the U.S. Attorney has declined to initiate legal proceedings in a case;

4. follow these guidelines when the individual or firm receiving the NOW submits an appeal:

a. review the letter and contact the RM or designee, as necessary, to obtain a copy of the ROI and discuss any findings;

b. evaluate and determine whether the evidence in the ROI supports the NOW letter;

c. if necessary, work with USDA's OGC and other program areas to make any legal determinations;

d. deny the appeal if EED determines that the evidence in the case supports the issuance of the NOW;

e. rescind the NOW if the evidence in the case does not support the issuance of the NOW letter;

f. inform the RM or designee that the NOW appeal is to be denied, or that the NOW is to be rescinded; and

g. prepare a written response to the individual or the company advising him or her, or the company, of the Agency's decision to rescind or deny the appeal and provide a copy of the letter to the RM or designee.

XII. ISSUING LETTERS OF INFORMATION

OPEER may issue LOIs when it has determined that an enforcement action is not warranted, but that it is necessary to advise individuals of the requirements under the statutes and to urge compliance. The main purpose of these letters is to establish awareness of the statutory and regulatory requirements. LOIs are issued by the RM or designee, although EED may issue them as well.

XIII. REFERRING ACTIONS TO OTHER AGENCIES

Using the criteria established in the MOU with OIG, CID and EED officials are to determine whether to refer the information obtained in an ROI concerning an alleged violation of the Acts to OIG. The OIG will determine whether to investigate (e.g., open a case memorandum) and, if appropriate, notify Federal, State, or local law enforcement officials or other authorities.

When appropriate, CID and EED officials will also coordinate with other Federal or State agencies on possible referrals for investigations or enforcement actions under other Federal and State programs.

Refer questions to the Technical Service Center at 1-800-233-3935.



Assistant Administrator
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